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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/548,403	07/27/2006	Marie Bendix Hansen	036179-0108	7935
23428 7590 09/23/2009 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007				
EXAMINER				
KIM, ALEXANDER D				
ART UNIT		PAPER NUMBER		
1656				
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09/23/2009		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/548,403

**Applicant(s)**

HANSEN ET AL.

**Examiner**

ALEXANDER D. KIM

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 July 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Application Status***

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/15/2009 has been entered.

Applicants' filed no claim amendment after the final rejection (mailed on 10/29/2008) or after the advisory action (mailed on 3/31/2009). Thus, the claims filed on 07/08/2008 is considered in the instant office action. However, applicants' argument in Remarks filed on 7/15/2009 is considered in the instant office action.

Claims 1-15 are pending and will be examined herein.

#### ***Withdrawn-Objections to the Specification***

2. The previous objection to the specification for replacing many period symbols with commas in various places, such as the "1.500" into "1,500" in page 3, line 25, is withdrawn by virtue of applicants argument and by virtue of reconsideration by the Examiner (i.e., "." was placed instead of "," which is an obvious error).

***Objections to the Specification***

3. The specification is objected to because of the following informalities:

In the specification, the Abstract is objected to for not completely describing the disclosed subject matter (see M.P.E.P. § 608.01(b)). It is noted that in many databases and in foreign countries, the Abstract is crucial in defining the disclosed subject matter, thus, its completeness is essential. In view of the obvious error reciting 1.500 instead of 1500 in the instant specification as noted above, the Examiner suggests the inclusion of such changes in the instant Abstract; thus, reciting 1500 cm/hour.

***Claim Objections***

4. Claim 14 is objected to because of the following informalities:

Claim 14 recites "wherein the volume applied is from about 2-3500 l/min". It should be ---2-3500 l--- since the volume should have unit represented by liter as correctly recited in Claim 15.

Appropriate correction is required.

***Withdrawn-Claim Rejections - 35 USC § 112***

5. The previous rejection of Claims 1-15 under 35 U.S.C. 112, first paragraph, new matter, as failing to comply with the written description requirement is withdrawn by virtue of applicants argument and by virtue of reconsideration by the Examiner (i.e., "." was placed instead of "," which is an obvious error).

6. The previous rejection of Claim 13 under 35 U.S.C. 112, first paragraph, **new matter**, as failing to comply with the written description requirement is withdrawn for the same reasons above; that is by virtue of applicants argument and by virtue of reconsideration by the Examiner (i.e., "." was placed instead of "," which is an obvious error).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3-5, 10-11, 13 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the

feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims.

Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 3-5, 10-11, 13 and 15 recites the broad recitation as disclosed in said claims, and the claims also recites the limitations as recited in said claims which is the narrower statement of the range/limitation.

- (b) Regarding claims 4 and 13, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Appropriate correction is required.

***Withdrawn-Claim Rejections - 35 USC § 103***

8. The previous rejection of Claims 1-15 under 35 U.S.C. 103(a) as being unpatentable over Kawakami et al. as evidenced by Hirai et al., Mitoma et al., Yashida et al. and Ahern is withdrawn by virtue of reconsideration of the Examiner (although, the applicants' argument is not persuasive); i.e., in view of the differences in operation procedures between a normal packed column and the "Expanded Bed Adsorption" (i.e., known as EBA for one skilled in the art).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claims 1-2, 5-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lihme et al. (WO 02/096215, published May 12, 2002) as evidenced by Molecular Weight of IgG (last viewed Sep. 11 2009).

Lihme et al. teach a method for purifying LP (lactoperoxidase) comprising steps: adjusting a pH of sweet whey; loading on column C at 50°C which teach bringing the bio-molecule-containing fluid to a temperature of 50°C since the sample has to be 50°C to operate EBA column at that temperature; applying the sample into a EBA column, eluting LP in view of LP eluted data shown in the Table at the bottom of page 36, see the Example 11. Lihme et al. also recites instant method steps in the Claim 1 on page 49; wherein the Claim 1 of Lihme et al. teach a method of performing an Expanded Bed adsorption column for fractionation of a sample in various conditions. More specifically, according to Claim 1 of Lihme et al., Lihme et al. teach a method for the fractionation of a protein-containing mixture wherein the protein-containing mixture is selected from the group consisting of **milk** (meeting instant claim 9), milk derived products, milk derived raw materials, vegetable derived products, vegetable derived extracts, fruit derived products, fruit derived extracts, fish derived products, and fish derived extracts, said

method comprising the steps of: a) optionally adjusting the pH of the mixture; b) applying said mixture to an adsorption column comprising an adsorbent, said adsorbent comprises a particle with at least one high density non-porous core, surrounded by a porous material, the adsorbent having a particle density of at least 1.5 g/ml and a mean particle size of at most 150  $\mu\text{m}$ ; c) optionally washing the column; d) eluting at least one protein from the adsorbent." Thus, meeting all limitations of instant Claim 1 except the flow rate of at least 1500 cm/hour. The Figure 6 shows that some of whey proteins have molecular weight similar to IgG (which is 150000 Daltons, see Molecular weight of IgG, page 2, top right).

Lihme et al. does not teach linear flow rate of at least 1500 cm/hour; a loading sample volume of at least 10 liters, 2-3500 l or at least 50 l in the Example 11 as noted above.

However, Lihme et al. teach "In the expanded bed state, the distance between the adsorbent particles result in a free passage of particulate impurities in the feed stream. By contrast, traditional packed beds work as depth filters that can clog, resulting in increased back-pressure unless the feed is thoroughly clarified. Since no significant pressure builds up in an EBA column, it is possible to apply EBA without the limitations in size and flow rate normally associated with packed- bed columns." (emphasis added, see page 2, lines 13-19). Furthermore, Lihme et al. also teach the method above to be performed at flow-rate of about 5-50 cm/min (i.e., about 3000 cm/hour) in view of Claim 2 on page 49. Lihme et al. also teach a method of EBA column chromatography by loading sample of 3180 l (i.e., liter) of whey sample onto an EBA column for purifying LP



(as shown in Example 18 on page 43, line 24). Lihme et al. teach the adsorbent mean particle size used in EBA column can be 59  $\mu\text{m}$  and density of 3.3 g/ml (see description of Figure 9 on page 9, lines 13-14); meeting the limitations of Claims 10-12.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify an Expanded Bed adsorption (EBA) column and/or process disclosed by Lihme et al. so that said method applies a higher flow rate (3000 cm/hour, for example), any size of biological sample (e.g., up to more than about 3000 liter) and/or many different size of adsorbent particle size (for example, 59  $\mu\text{m}$  particle size with density of 3.3 g/ml as noted above) with a reasonable expectation of success because Lihme et al. teach the sample size and flow rate is not limitations in EBA column system. The motivation to do so is provided by Lihme et al. who teach the usefulness of Expanded Bed Adsorption column is "more efficient and cost effective production method" in a chromatographic separation technique in the field of biotechnology industry (see page 1, lines 30-36). Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

9. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lihme et al. (WO 02/096215, published May 12, 2002) as evidenced by Molecular Weight of IgG (last viewed Sep. 11 2009) as applied to claims 1-2, 5-15 above, and **further in view of** Olander et al., (Scandinavian Dairy Information, 2001, no. 2., pp. 22-25).

The teachings of Lihme et al. as evidenced by "Molecular Weight of IgG" are shown as set forth above.

Lihme et al. as evidenced by "Molecular Weight of IgG" do not teach a EBA column having about 100 to 1000 l of adsorbent (instant Claim 3); and having a diameter of about 50 cm to 200 cm (instant Claim 4).

Orlander et al. teach an industrial scale EBA column having 265 liters of adsorbent and having a diameter of 1.5 meter (i.e., 1500 cm), see bottom of left column, page 25.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify an Expanded Bed adsorption (EBA) column and/or process disclosed by Lihme et al. so that said method use a large industrial scale EBA column as disclosed by Orlander et al. with a reasonable expectation of success because it is well known for one skilled in the art to make and use appropriate size of column for a volume of sample of interest as shown by Lihme et al. who teach the sample size and flow rate is not limitations in EBA column system. The motivation to increase or adjust the EBA column size so is provided by Lihme et al. who teach the usefulness of "more efficient and cost effective production method" in a chromatographic separation techniques in the field of biotechnology industry (see page 1, lines 30-36); or Orlander et al. who disclose the industry scale (i.e., a large EBA column) EBA technology is "a cost-effective industrial-scale method for production of components from whey and milk" (see top of left column, page 22). Thus, the claimed

invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Conclusion***

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEXANDER D. KIM whose telephone number is (571)272-5266. The examiner can normally be reached on 10AM-6:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alexander D Kim/  
Examiner, Art Unit 1656